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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,432	11/21/2001	Jules B. Puschett	205204-00009	4234
7590 06/22/2004			EXAMINER	
Arnold B. Silverman Eckert Seamans Cherin & Mellott, LLC 600 Grant Street - 44th Floor Pittsburgh, PA 15219			GABEL, GAILENE	
			ART UNIT	PAPER NUMBER
			1641	
DATE MAILED: 06/22/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/990,432

Applicant(s)

PUSCHETT, JULES B.

Examiner

Gailene R. Gabel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 19-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-37 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/17/02.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-18, without traverse, filed on 4/8/04, is acknowledged and has been entered. Claims 19-37 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention. Accordingly, claims 1-37 are pending. Claims 1-18 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "similar or identical" in claim 1 recites relative terms which render the claim indefinite. The phrase "similar or identical" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Claim 1 is vague and indefinite in reciting "similar or identical" because it fails

to adequately establish and specifically define how the recited elements are similar/identical, i.e. in molecular weight, physiological function, genetic sequence, etc.

The term "substantial" in claim 1 is a relative term which renders the claim indefinite. The term "substantial" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. See also claim 9.

Claim 1 is confusing in reciting, "employing CLAMP as said protein" because it is unclear as recited how "CLAMP" is being employed as a protein in the claim. Claim 1 is also vague and indefinite in lacking clear antecedent basis in reciting, "employing CLAMP as said protein" because the protein recited supra does not appear to be "used or employed" in the claim. The protein instead is recited as being 1) contained in a body specimen, 2) detected for its concentration or phosphorylation, and 3) determined for concentration or phosphorylation in comparison to normal patients.

Claim 1 is indefinite in reciting, "CLAMP". Acronyms or abbreviations, if any, must be fully defined and recited at least one time in a set of claims.

Claim 2 is non-idiomatic and, therefore, confusing in reciting "including". It is unclear what other elements should be "included" in the claim. Perhaps, Applicant intends "comprising". It is further unclear how blood is employed as the body specimen. Perhaps Applicant intends, "wherein the body specimen (obtained) is blood".

Claim 3 is non-idiomatic and, therefore, confusing in reciting "including". It is unclear what other elements should be "included" in the claim. Perhaps, Applicant

intends "comprising". It is further unclear how urine is employed as the body specimen. Perhaps Applicant intends, "wherein the body specimen (obtained) is urine".

Claim 4 is non-idiomatic and, therefore, confusing in reciting "including". It is unclear what other elements should be "included" in the claim. Perhaps, Applicant intends "comprising". It is further unclear how blood-derived protein is employed as the protein. Perhaps Applicant intends, "wherein the protein (contained in the body specimen obtained) is blood-derived protein".

Claim 5 is non-idiomatic and, therefore, confusing in reciting "including". It is unclear what other elements should be "included" in the claim. Perhaps, Applicant intends "comprising".

Claim 5 is vague and indefinite because it is unclear what Applicant intends to encompass in reciting, "effecting". Perhaps Applicant intends, "performing or obtaining".

Claim 6 is non-idiomatic and, therefore, confusing in reciting "including". It is unclear what other elements should be "included" in the claim. Perhaps, Applicant intends "comprising".

Claim 6 is vague and indefinite because it is unclear what Applicant intends to encompass in reciting, "effecting". Perhaps Applicant intends, "performing or obtaining". Perhaps, Applicant intends "comprising".

Claim 10 is non-idiomatic and, therefore, confusing in reciting "including". It is unclear what other elements should be "included" in the claim. Perhaps, Applicant intends "comprising".

Claim 12 is vague and indefinite because it is unclear how blood serum from the human patient is employed as a source of said blood-derived protein. Perhaps Applicant intends, "wherein the blood-derived protein for determining ... is obtained from blood serum".

Claim 15 is vague and indefinite because it is unclear how blood plasma from the human patient is employed as a source of said blood-derived protein. Perhaps Applicant intends, "wherein the blood-derived protein for determining ... is obtained from blood plasma".

Claim 17 is vague and indefinite because it is unclear how cellular element of the blood obtained from the human patient is employed as a source of said blood-derived protein. Does Applicant intend, "wherein the blood-derived protein is obtained from cellular element of the blood".

Regarding claim 18, the phrase "other types of hypertension" renders the claim indefinite because the claim includes elements not actually disclosed (those encompassed by "other types"), thereby rendering the scope of the claim unascertainable. See MPEP § 2173.05(d).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

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1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-18 are rejected under the judicially created doctrine of double patenting over claims 1-11 of U. S. Patent No. 6,251,611 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a method of determining chronic volume dependent hypertension by determining a 20-30 percent reduction in phosphorylation of a blood-derived protein having Mr = 72,000 Daltons, which may be CLAMP protein, and which is identical to renal brush border membrane protein, wherein a 20-30 percent reduction in phosphorylation or concentration of the protein is indicative of chronic volume dependent hypertension.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

4. Claims 1-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,251,611. Although the conflicting claims are not identical, they are not patentably distinct from each other because as Applicant, by way of disclosure at page 3, line 1 and page 14, line 22 to page 15, line 22 of the specification, admits that the blood-derived protein having Mr = 72,000 Daltons, which is identical to renal brush border membrane protein in US Patent 6,251,611, is CLAMP protein as currently recited in the instant invention, and which is also recited as being used in the method of determining chronic volume dependent hypertension wherein a 20-30 percent reduction in concentration or phosphorylation of the CLAMP protein is indicative of chronic volume dependent hypertension.

6. No claims are allowed.

Remarks

7. Prior art made of record are not relied upon but considered pertinent to the applicants' disclosure:

Ikemoto et al. (PNAS 97(12): 6538-6543 (June 6, 2000)) identifies a PDZ-domain-containing protein that intersects with the scavenger receptor class B type I protein denoted it as CLAMP or C-terminal linking and modulating protein.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 5:30 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gailene R. Gabel
Patent Examiner
Art Unit 1641
June 14, 2004

Christopher L. Chin
CHRISTOPHER L. CHIN
PRIMARY EXAMINER
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